

**REMARKS**

In the Office Action mailed August 13, 2002, the Examiner presumed that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made. The subject matter of all claims was commonly owned at the time inventions covered therein were made.

The Examiner also rejected claims 1-7 as being anticipated or obvious in view of prior art. Claim 1 has been amended. Claims 8-33 have been added to further define the invention. Reconsideration of the outstanding rejection is respectfully requested in view of the foregoing amendments and the following remarks.

**Rejections in view of combined references**

Claims 1-7 were rejected as being obvious over Khan et al. (US Patent 5,439,681) in view of Kaiser et al. (US Patent 5,955,408). Applicant respectfully asserts that there is no proper basis for combining these references as proposed by the Examiner and that, even if combined, these references do not teach or suggest each element of the pending claims.

Hand washing by healthcare professionals is an essential component of infection control activities. Historically, the healthcare industry has used scrub brushes impregnated with antimicrobial agents for surgical scrub procedures. More recently, the industry has turned to a "brushless" surgical scrub technique where antimicrobial solutions are dispensed as liquid soap and a scrub brush is not used. Khan and Kaiser fall into this category. Their formulations are designed to be employed in a liquid that is delivered to the skin and, as such, have characteristics appropriate for that use.

The instant invention is directed to a *foamable* cleansing formulation. It is intended to be dispensed from a foam-forming dispensing device, such as those disclosed in U.S. Patents 6,053,369 and 6,308,866. Consequently, the formulation of the instant invention is designed to have different characteristics than soaps intended for dispensing in liquid form. As discussed

below, one skilled in the art would not be disposed to combine the teaching of two liquid soaps (such as in Kahn and Kaiser) to achieve a formulation useful for foamable cleansing solutions, particularly since neither Khan nor Kaiser teach or suggest use with a foamable dispenser or dispensing as a foam.

Khan discloses an antimicrobial formulation comprising 0.5% to 3.75% by weight of parachlorometaxylenol (PCMX) antimicrobial agent; from 1 to 6% by weight of a nonionic surfactant; from 2 to 12% by weight of an anionic surfactant; from 0.1 to 1% by weight of a thickener; from 2 to 12% by weight of a foam builder amphoteric surfactant; and from 60 to about 85% by weight of water. Khan notes that emollients may also be added. The pH of the Khan et al formulation is controlled to a range of 4.0 to 6.0.

Kaiser discloses a formulation comprising 0.2 to 3% by weight of triclosan; from 2.0 to 20% by weight of a combination of anionic and nonionic surfactants including isethionate; from 0.0 to 3.0% of a thickener, from 1.0 to 30% of emollients; and the remainder being water. The viscosity of the composition is controlled to be from 20 to 10,000 cps and the pH is between 3.5 and 8.0.

The Examiner proposes that the teachings of Khan and Kaiser can be combined to achieve the claimed invention. It should be noted that neither of these references teaches use of their formulations in a foamable dispenser. Claims of the instant application recite a foamable antimicrobial formulation having a low viscosity - of about 10 cps in certain cases. Neither the Khan nor the Kaiser formulations have a viscosity of less than 20 cps. Rather, both Khan and Kaiser include a thickening agent, such as methylcellulose, to increase the viscosity of the composition - thus teaching away from this aspect of the instant invention. The thickening agent of Khan and Kaiser creates an antimicrobial composition having a viscosity that will not easily spill from the healthcare worker hand, which is useful when the formulation is intended to be dispensed as a liquid as in Khan and Kaiser. In contrast, the formulations of the instant invention are intended to be dispensed as foam. Therefore, a higher viscosity is not

required and in fact is detrimental to the generation of foam. Aspects of the instant invention are directed to formulations having a lower viscosity — directly contrary to the teachings of Kahn and Kaiser. It is noted that if a thickening agent were added to the formulations of the present invention, the viscosity would increase, causing the foam density to decrease. Table IV of the instant application illustrates the affect of adding a thickening agent to the instant composition. Foam volume decreases from 700ml to <10ml as viscosity increases from 9.5 cps to 200 cps. The foam volume is above 300 ml when the viscosity is less than about 20 cps resulting in a highly foamable solution. Consequently, one would not be disposed to modify Khan or Kaiser to develop characteristics of low viscosity and high foamability that are not useful or desirable for the formulations of either reference.

#### Rejection in view of Kaiser

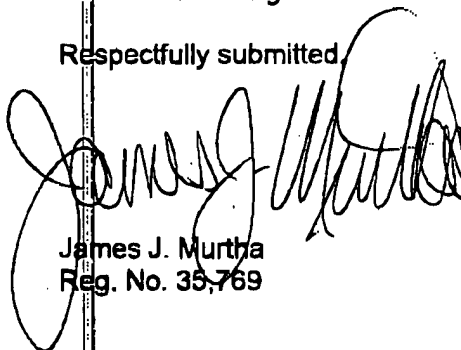
Claims 1-7 were rejected as being obvious over Kaiser. Kaiser discloses a disinfectant composition comprising anionic surfactants such as isethionates. Isethionate is a well-known surfactant and is used in the Kaiser composition as an agent to solubilize the triclosan antimicrobial agent. Only certain surfactants create an appropriate chemical condition for the solubilization of antimicrobial agents such as triclosan. Kaiser discloses the combination of anionic and nonionic surfactants to achieve this solubilization. Kaiser also discloses a composition viscosity range of 20 cps to 10,000 cps. In contrast, the present composition utilizes a combination of anionic, nonionic and amphoteric surfactants to solubilize antimicrobial agents such as triclosan and PCMX. Isethionate is used in the present composition in addition to other surfactants as a foam booster to facilitate the generation of a higher volume of foam from a foam-generating dispenser. The mere addition of isethionate to the composition is not adequate to promote a desirable volume of foam. Rather, the instant invention also requires a low viscosity. Table III of the present application shows that the addition of isethionate to a composition does not necessarily result in a foamable solution. The viscosity must also be low

to generate the desired volume of foam. A composition combining an isethionate surfactant and a low viscosity are not disclosed in the prior art and would not be obvious to someone skilled in the art. One would not be motivated to add isethionate to Khan and to decrease the viscosity of the Khan composition. The result would be a composition with poor characteristics for an antimicrobial cleansing composition that is dispensed as a liquid.

### CONCLUSION

The claims of the instant application are believed patentable over the art of record. Reconsideration of the outstanding rejections is therefore respectfully requested. Should any issues remain outstanding, the Examiner is invited to call the undersigned.

Respectfully submitted,



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